

Substitute for form 1449A/PTO

**Complete if Known**

*(use as many sheets as necessary)*

Sheet	1	of	6 sheets
-------	---	----	----------

Application Number	10/699,597
Filing Date	10/30/2003
First Named Inventor	Draghia-Akli, et al.
Group Art Unit	1633
Examiner Name	Marvich
Attorney Docket Number	108328.00161 (AVSI-0027)

[illegible]

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				

**Examiner  
Signature**

/Maria Marvich/

Date  
Considered

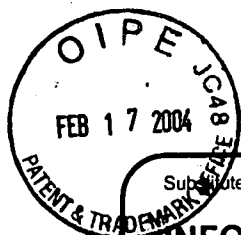
09/27/2008

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04.

<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, DC 20231.



Supplement for form 1449A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

*(use as many sheets as necessary)*

Sheet 2 of 6 sheets

## Complete if Known

Application Number	10/699,597
Filing Date	10/30/2003
First Named Inventor	Draghia-Akli, Ruxandra
Group Art Unit	
Examiner Name	
Attorney Docket Number	108328.00161

## OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
/M.M./	2	ACSADI, G., S. S. Jiao, A. Jani, D. Duke, P. Williams, W. Chong, and J. A. Wolff. 1991. Direct gene transfer and expression into rat heart in vivo. <i>New Biologist</i> 3:71-81.	
/M.M./	3	BARNHART, K., J. Hartikka, M. Manthorpe, J. Norman, and Hobart P. 1998. Enhancer and promoter chimeras in plasmids designed for intramuscular injection : a comparative in vivo and in vitro study. <i>American Society of Gene Therapy-1st Annual Meeting Abstract</i> 303.	
/M.M./	4	BERGSMA, D. J., J. M. Grichnik, L. M. Gossett, and R. J. Schwartz. 1986. Delimitation and characterization of cis-acting DNA sequences required for the regulated expression and transcriptional control of the chicken skeletal alpha-actin gene. <i>Molecular &amp; Cellular Biology</i> 6:2462-2475.	
/M.M./	5	BUVOLI, M., S. J. Langer, S. Bialik, and L. A. Leinwand. 2002. Potential limitations of transcription terminators used as transgene insulators in adenoviral vectors. <i>Gene Ther.</i> 9:227-231.	
/M.M./	6	CARROLL, S. L., D. J. Bergsma, and R. J. Schwartz. 1986. Structure and complete nucleotide sequence of the chicken alpha- smooth muscle (aortic) actin gene. An actin gene which produces multiple messenger RNAs. <i>J. Biol. Chem.</i> 261:8965-8976.	
/M.M./	7	CHANG, P. S., L. Li, J. McAnally, and E. N. Olson. 2001. Muscle specificity encoded by specific serum response factor-binding sites. <i>J. Biol. Chem.</i> 276:17206-17212.	
/M.M./	8	CHOW, K. L., M. E. Hogan, and R. J. Schwartz. 1991. Phased cis-acting promoter elements interact at short distances to direct avian skeletal alpha-actin gene transcription. <i>Proc. Natl. Acad. Sci. USA</i> 88:1301-1305.	
/M.M./	9	CHOW, K. L. and R. J. Schwartz. 1990. A combination of closely associated positive and negative cis- acting promoter elements regulates transcription of the skeletal alpha-actin gene. <i>Molecular &amp; Cellular Biology</i> 10:528-538.	
/M.M./	10	CONDORELLI, G., R. Roncarati, J. Ross, Jr., A. Pisani, G. Stassi, M. Todaro, S. Trocha, A. Drusco, Y. Gu, M. A. Russo, G. Frati, S. P. Jones, D. J. Lefer, C. Napoli, and C. M. Croce. 2001. Heart-targeted overexpression of caspase3 in mice increases infarct size and depresses cardiac function. <i>Proc. Natl. Acad. Sci. U. S. A</i> 98:9977-9982.	
/M.M./	11	DING, E., H. Hu, B. L. Hodges, F. Migone, D. Serra, F. Xu, Y. T. Chen, and A. Amalfitano. 2002. Efficacy of gene therapy for a prototypical lysosomal storage disease (GSD-II) is critically dependent on vector dose, transgene promoter, and the tissues targeted for vector transduction. <i>Mol. Ther.</i> 5:436-446.	

Examiner  
Signature

/Maria Marvich/

Date  
Considered

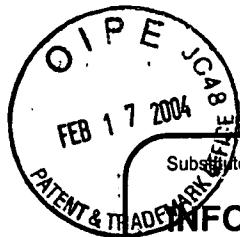
09/27/2008

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

3462237v1 108328/00161



Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 3 of 6 sheets

**Complete if Known**

Application Number	10/699,597
Filing Date	10/30/2003
First Named Inventor	Draghia-Akli, Ruxandra
Group Art Unit	
Examiner Name	
Attorney Docket Number	108328.00161

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
/M.M./	12	DRAGHIA-AKLI, R., M. L. Fiorotto, L. A. Hill, P. B. Malone, D. R. Deaver, and R. J. Schwartz. 1999. Myogenic expression of an injectable protease-resistant growth hormone-releasing hormone augments long-term growth in pigs. Nat. Biotechnol. 17:1179-1183.	
/M.M./	13	DRAGHIA-AKLI, R., X. G. Li, and R. J. Schwartz. 1997. Enhanced growth by ectopic expression of growth hormone releasing hormone using an injectable myogenic vector. nature biotechnology 15:1285-1289.	
/M.M./	14	FRANZ, W. M., T. Rothmann, N. Frey, and H. A. Katus. 1997. Analysis of tissue-specific gene delivery by recombinant adenoviruses containing cardiac-specific promoters. Cardiovasc. Res. 35:560-566.	
/M.M./	15	GOSSETT, L. A., D. J. Kelvin, E. A. Sternberg, and E. N. Olson. 1989. A new myocyte-specific enhancer-binding factor that recognizes a conserved element associated with multiple muscle-specific genes. Molecular & Cellular Biology 9:5022-5033.	
/M.M./	16	HARTIKKA, J., M. Sawdey, F. Cornefert-Jensen, M. Margalith, K. Barnhart, M. Nolasco, H. L. Vahlsing, J. Meek, M. Marquet, P. Hobart, J. Norman, and M. Manthorpe. 1996. An improved plasmid DNA expression vector for direct injection into skeletal muscle. Human Gene Therapy 7:1205-1217.	
/M.M./	17	HAYWARD, L. J. and R. J. Schwartz. 1986. Sequential expression of chicken actin genes during myogenesis. Journal of Cell Biology 102:1485-1493.	
/M.M./	18	KELLY, K. K., S. M. Meadows, and R. M. Cripps. 2002. Drosophila MEF2 is a direct regulator of Actin57B transcription in cardiac, skeletal, and visceral muscle lineages. Mech. Dev. 110:39-50.	
/M.M./	19	KEOGH, M. C., D. Chen, J. F. Schmitt, U. Dennehy, V. V. Kakkar, and N. R. Lemoine. 1999. Design of a muscle cell-specific expression vector utilising human vascular smooth muscle alpha-actin regulatory elements. Gene Ther. 6:616-628.	
/M.M./	20	LARKIN, S. B., I. K. Farrance, and C. P. Ordahl. 1996. Flanking sequences modulate the cell specificity of M-CAT elements. Molecular & Cellular Biology 16:3742-3755.	
/M.M./	21	LASSAR, A. B., R. L. Davis, W. E. Wright, T. Kadesch, C. Murre, A. Voronova, D. Baltimore, and H. Weintraub. 1991. Functional activity of myogenic HLH proteins requires hetero-oligomerization with E12/E47-like proteins in vivo. Cell 66:305-315.	

Examiner  
Signature

/Maria Marvich/

Date  
Considered

09/27/2008

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 4 of 6 sheets

**Complete if Known**

Application Number	10/699,597
Filing Date	10/30/2003
First Named Inventor	Draghia-Akli, Ruxandra
Group Art Unit	
Examiner Name	
Attorney Docket Number	108328.00161

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
/M.M./	22	LEE, T. C., Y. Shi, and R. J. Schwartz. 1992. Displacement of BrdUrd-induced YY1 by serum response factor activates skeletal alpha-actin transcription in embryonic myoblasts. Proc. Natl. Acad. Sci. USA 89:9814-9818.	
/M.M./	23	LEE, T. C., Y. Zhang, and R. J. Schwartz. 1994. Bifunctional transcriptional properties of YY1 in regulating muscle actin and c-myc gene expression during myogenesis. Oncogene 9:1047-1052.	
/M.M./	24	LI, X., E. M. Eastman, R. J. Schwartz, and R. Draghia-Akli. 1999. Synthetic muscle promoters: activities exceeding naturally occurring regulatory sequences. nature biotechnology 17:241-245.	
/M.M./	25	LIN, H., M. S. Parmacek, G. Morle, S. Bolling, and J. M. Leiden. 1990. Expression of recombinant genes in myocardium in vivo after direct injection of DNA. Circulation 82:2217-2221.	
/M.M./	26	MACHON, O., J. Svoboda, J. Geryk, J. Hejnar, and V. Strmen. 1998. Sp1 binding sites inserted into the rous sarcoma virus long terminal repeat enhance LTR-driven gene expression. Gene 208 (1):73-82.	
/M.M./	27	MAZDA, O. 2002. Improvement of nonviral gene therapy by Epstein-Barr virus (EBV)-based plasmid vectors. Curr. Gene Ther. 2:379-392.	
/M.M./	28	MINTY, A. and L. Kedes. 1986. Upstream regions of the human cardiac actin gene that modulate its transcription in muscle cells: presence of an evolutionarily conserved repeated motif. Molecular & Cellular Biology 6:2125-2136.	
/M.M./	29	MONTGOMERY, D. L., J. B. Ulmer, J. J. Donnelly, M. A. Liu, Immunization, Antibodies, Cell-mediated immunity, Protective immunity, Foreign-gene expression, and Plasmid vectors. 1997. DNA vaccines. Pharmacology & Therapeutics 74:195-205.	
/M.M./	30	NEMER, G. and M. Nemer. 2001. Regulation of heart development and function through combinatorial interactions of transcription factors. Ann. Med. 33:604-610.	
/M.M./	31	O'CONNELL, T. D., D. G. Rokosh, and P. C. Simpson. 2001. Cloning and characterization of the mouse alpha1C/A-adrenergic receptor gene and analysis of an alpha1C promoter in cardiac myocytes: role of an MCAT element that binds transcriptional enhancer factor-1 (TEF-1). Mol. Pharmacol. 59:1225-1234.	

Examiner  
Signature

/Maria Marvich/

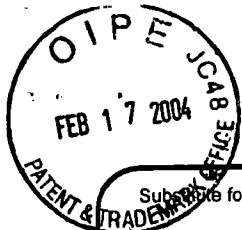
Date  
Considered

09/27/2008

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 5 of 6 sheets

**Complete if Known**

Application Number	10/699,597
Filing Date	10/30/2003
First Named Inventor	Draghia-Akli, Ruxandra
Group Art Unit	
Examiner Name	
Attorney Docket Number	108328.00161

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
/M.M./	32	OLSON, E. N., T. J. Brennan, T. Chakraborty, T. C. Cheng, P. Cserjesi, Edmondson, G. James, and L. Li. 1991. Molecular control of myogenesis: antagonism between growth and differentiation. Molecular & Cellular Biochemistry 104:7-13.	
/M.M./	33	PHILLIPS, M. I., Y. Tang, K. Schmidt-Ott, K. Qian, and S. Kagiya. 2002. Vigilant vector: heart-specific promoter in an adeno-associated virus vector for cardioprotection. Hypertension 39:651-655.	
/M.M./	34	PRENTICE, H., R. A. Kloner, Y. Li, L. Newman, and L. Kedes. 1996. Ischemic/reperfused myocardium can express recombinant protein following direct DNA or retroviral injection. J. Mol. Cell Cardiol. 28:133-140.	
/M.M./	35	ROELL, W., Y. Fan, Y. Xia, E. Stoecker, P. Sasse, E. Kolossov, W. Bloch, H. Metzner, C. Schmitz, K. Addicks, J. Hescheler, A. Welz, and B. K. Fleischmann. 2002. Cellular cardiomyoplasty in a transgenic mouse model. Transplantation 73:462-465.	
/M.M./	36	ROTHERMEL, B. A., T. A. McKinsey, R. B. Vega, R. L. Nicol, P. Mammen, J. Yang, C. L. Antos, J. M. Shelton, R. Bassel-Duby, E. N. Olson, and R. S. Williams. 2001. Myocyte-enriched calcineurin-interacting protein, MCIP1, inhibits cardiac hypertrophy in vivo. Proc. Natl. Acad. Sci. U. S. A 98:3328-3333.	
/M.M./	37	SCHWARTZ, R. J. and K. N. Rothblum. 1981. Gene switching in myogenesis: differential expression of the chicken actin multigene family. Biochemistry 20:4122-4129.	
/M.M./	38	SKARLI, M., A. Kiri, G. Vrbova, C. A. Lee, and G. Goldspink. 1998. Myosin regulatory elements as vectors for gene transfer by intramuscular injection. Gene Therapy 5:514-520.	
/M.M./	39	STEWART, A. F., S. B. Larkin, I. K. Farrance, J. H. Mar, D. E. Hall, and C. P. Ordahl. 1994. Muscle-enriched TEF-1 isoforms bind M-CAT elements from muscle-specific promoters and differentially activate transcription. J. Biol. Chem. 269:3147-3150.	
/M.M./	40	VALE, P. R., D. W. Losordo, T. Tkebuchava, D. Chen, C. E. Milliken, and J. M. Isner. 1999. Catheter-based myocardial gene transfer utilizing nonfluoroscopic electromechanical left ventricular mapping. J. Am. Coll. Cardiol. 34:246-254.	
/M.M./	41	WANG, D., P. S. Chang, Z. Wang, L. Sutherland, J. A. Richardson, E. Small, P. A. Krieg, and E. N. Olson. 2001. Activation of cardiac gene expression by myocardin, a transcriptional cofactor for serum response factor. Cell 105:851-862.	

Examiner  
Signature

/Maria Marvich/

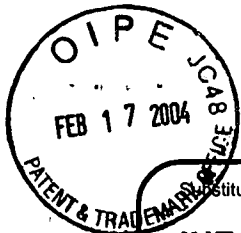
Date  
Considered

09/27/2008

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.  
3462237v1 108328/00161



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	10/699,597		
		Filing Date	10/30/2003		
		First Named Inventor	Draghia-Akli, Ruxandra		
		Group Art Unit			
		Examiner Name			
Sheet	6	of	6 sheets	Attorney Docket Number	108328.00161

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
/M.M./	42	WEBSTER, K. A. and N. H. Bishopric. 2000. Molecular aspects and gene therapy prospects for diastolic failure. Cardiol. Clin. 18:621-635.	
/M.M./	43	WEINTRAUB, H., R. Davis, D. Lockshon, and A. Lassar. 1990. MyoD binds cooperatively to two sites in a target enhancer sequence: occupancy of two sites is required for activation. Proc. Natl. Acad. Sci. USA 87:5623-5627.	
/M.M./	44	WOLFF, J. A., J. J. Ludtke, G. Acsadi, P. Williams, and A. Jani. 1992. Long-term persistence of plasmid DNA and foreign gene expression in mouse muscle. Human Molecular Genetics 1:363-369.	
/M.M./	45	XU, Z. L., H. Mizuguchi, A. Ishii-Watabe, E. Uchida, T. Mayumi, and T. Hayakawa. 2002. Strength evaluation of transcriptional regulatory elements for transgene expression by adenovirus vector. J. Control Release 81:155-163.	
/M.M./	46	ZHANG, X., J. Chai, G. Azhar, P. Sheridan, A. M. Borras, M. C. Furr, K. Khrapko, J. Lawitts, R. P. Misra, and J. Y. Wei. 2001. Early postnatal cardiac changes and premature death in transgenic mice overexpressing a mutant form of serum response factor. J. Biol. Chem. 276:40033-40040.	

Examiner Signature	/Maria Marvich/	Date Considered	09/27/2008
-----------------------	-----------------	--------------------	------------

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.